

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

<b>UNITED STATES OF AMERICA, <i>ex rel.</i></b>	:	
<b>DILBAGH SINGH, M.D., PAUL KIRSCH, M.D.,</b>	:	
<b>V. RAO NADELLA, M.D., and</b>	:	<b>Civil Action No. 04-186E</b>
<b>MARTIN JACOBS, M.D.,</b>	:	
	:	
<b>Relators,</b>	:	
	:	
<b>v.</b>	:	
	:	
<b>BRADFORD REGIONAL MEDICAL CENTER,</b>	:	
<b>V &amp; S MEDICAL ASSOCIATES, LLC,</b>	:	
<b>PETER VACCARO, M.D.,</b>	:	
<b>KAMRAN SALEH, M.D.,</b>	:	
<b>and DOES I through XX,</b>	:	
	:	
<b>Defendants.</b>	:	

**ANSWER AND NEW MATTER**

Defendant Bradford Regional Medical Center ("BRMC"), through its undersigned attorneys, answers the Complaint as follows:

1. Denied.
2. Denied.
3. Denied.
4. Denied.
5. Denied.
6. Denied.
7. Denied.
8. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

9. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
10. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
11. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
12. Admitted.
13. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
14. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
15. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
16. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
17. Denied.
18. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
19. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
20. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
21. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
22. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.

23. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
24. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
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33. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
34. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
35. Denied.
36. Admitted.

- 37. Admitted.
- 38. Admitted.
- 39. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
- 40. Admitted.
- 41. Admitted.
- 42. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
- 43. Denied.
- 44. Denied.
- 45. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
- 46. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
- 47. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
- 48. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
- 49. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
- 50. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
- 51. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
- 52. Denied.
- 53. Denied.

54. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
55. Denied.
56. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
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59. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
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63. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
64. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
65. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
66. It is admitted that BRMC sought reimbursement from state Medicaid programs. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in this Paragraph. Strict proof of the same is demanded.

- 67. It is admitted that BRMC is enrolled in and sought reimbursement from CHAMPUS/Tricare. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in this Paragraph. Strict proof of the same is demanded.
- 68. Admitted.
- 69. Admitted.
- 70. Admitted.
- 71. The allegations contained in this Paragraph are conclusions of law to which no response is required. To the extent that a response is required, said allegations are denied.
- 72. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
- 73. It is admitted that BRMC submitted requests for reimbursement from CHAMPUS/Tricare. Except as so admitted, the remaining allegations in this Paragraph are denied.
- 74. Denied.
- 75. Denied.
- 76. Denied.
- 77. Denied.
- 78. Denied.
- 79. Denied.
- 80. It is admitted that BRMC agreed to sublease nuclear cardiology equipment from V&S. Except as so admitted, the remaining allegations in this Paragraph are denied.
- 81. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.
- 82. Denied. It is further averred that said Agreement speaks for itself.
- 83. Denied.

84. Denied.

85. Denied.

86. Denied.

87. Denied.

88. Denied.

89. BRMC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph. Strict proof of the same is demanded.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

94. BRMC repeats the responses contained in Paragraphs 1 through 93 above as if fully set forth herein.

95. Denied.

96. Denied.

97. BRMC repeats the responses contained in Paragraphs 1 through 96 above as if fully set forth herein.

98. Denied.

99. Denied.

100. BRMC repeats the responses contained in Paragraphs 1 through 99 above as if fully set forth herein.

101. Denied.

102. Denied.

103. BRMC repeats the responses contained in Paragraphs 1 through 102 above as if fully set forth herein.

104. Denied.

105. Denied.

## **DEFENSES**

106. Defendants incorporate paragraphs 1 through 105 of their Answer as if fully restated herein, and interpose the following Defenses to the claims asserted by the Plaintiffs:

### **First Defense**

#### **Failure to State a Claim**

107. The Complaint fails to state a claim against Defendants for which relief can be granted.

### **Second Defense**

#### **Good Faith**

108. BRMC and its officers and directors reasonably believed and continue to believe that any and all financial relationships that exist or may have existed between BRMC on the one hand and V&S Medical Associates, Dr. Saleh and/or Dr. Vaccaro on the other comply with all applicable laws and regulations.

109. Any certification that BRMC may have made to the Government on its cost reports or otherwise relative to compliance with applicable rules and regulations was believed not to be false and did not violate the False Claims Act.

110. To the extent that any of the actions alleged by the Relators to have been taken by BRMC occurred, said actions were taken in good faith and not with any improper or illegal purpose or intent.



**Third Defense**

**Lack of Standing**

- 111. The United States Government has declined to intervene in this action.
- 112. None of the Relators have alleged to have suffered or have suffered any harm or injury as a result of any of the actions alleged to have been taken by the Defendants.
- 113. Insofar as Relators have not suffered harm as a result of Defendants' alleged actions and the Government has declined to intervene, Relators lack standing to bring this Action.

**Fourth Defense**

**Compliance with Anti-kickback Safe Harbors**

- 114. Any and all financial relationships that may have existed between BRMC on the one hand and V&S Medical Associates, Dr. Saleh and/or Dr. Vaccaro on the other comply with applicable "safe harbor" regulations promulgated under the Medicare Anti-kickback statute at 42 C.F.R. § 1001.952. Therefore, any certification that BRMC may have made to the Government on its cost reports or otherwise relative to compliance with applicable rules and regulations was not false and did not violate the False Claims Act.

**Fifth Defense**

**Compliance with Stark Law Exceptions**

- 115. Any and all financial relationships that may have existed between BRMC on the one hand and V&S Medical Associates, Dr. Saleh and/or Dr. Vaccaro on the other comply with applicable exceptions set forth in the Physician Self-referral statute (the "Stark Law"), 42 U.S.C. § 1395nn, and the regulations thereunder at 42 C.F.R. § 411.350 to § 411.361. Therefore, any certification that BRMC may have made to the Government

on its cost reports or otherwise relative to compliance with applicable rules and regulations was not false and did not violate the False Claims Act.

### **Sixth Defense**

#### **Lack of Financial Relationship Covered by Stark Law**

116. The lease between BRMC and V&S Medical Associates which was appended to the Relators' Complaint does not constitute a "financial relationship" between BRMC and either Dr. Saleh or Dr. Vaccaro as that term is defined in the Stark Law 42 U.S.C. § 1395nn, or the regulations thereunder at 42 C.F.R. § 411.350 to § 411.361.

### **Seventh Defense**

#### **Certification of Compliance Not a Condition of Payment**

117. The certifications of compliance contained in the Medicare cost reports referred to in Relators' Complaint are not required as a condition of payment by Medicare, Medicaid or CHAMPUS. Therefore, even if said certifications were incorrect or false, that fact would not give rise to an action under the False Claims Act.

### **Eighth Defense**

#### **Complaint Based on Cost Reports That Were Not Filed**

118. The Medicare, Medicaid and CHAMPUS cost reports covering the cost reporting periods when the lease between BRMC and V&S Medical Associates was in effect were not filed and could not have been filed until long after the date that the Complaint was filed. Therefore, no certifications of compliance with applicable laws and regulations that may have been contained in those cost reports were made at the time the Complaint was filed.

**Ninth Defense**

**Lack of Subject Matter Jurisdiction**

119. This Court lacks subject matter jurisdiction over this matter.

**Tenth Defense**

**Lack of Wrongful Conduct**

120. BRMC did not present or cause to be presented any false claim, record or statement to the United States Government.
121. BRMC did not violate any provisions of Pennsylvania or Federal law.
122. BRMC did not breach any duties under the laws, rules or regulations of the Commonwealth of Pennsylvania or the Federal Government.
123. BRMC did not engage in any wrongful conduct, any knowing misrepresentations, or any fraud with respect to the Commonwealth of Pennsylvania or the United States of America.

**Eleventh Defense**

**Unconstitutionality of False Claims Act**

124. To the extent that penalties under the False Claims Act grossly exceed any actual damage incurred by the Government as a result of any claims paid, said Act violates the Excessive Fines Clause of the Eighth Amendment to the United States Constitution, and therefore is void.

WHEREFORE, BRMC prays this Honorable Court to dismiss all claims against it, with prejudice, and to award BRMC all costs and such other relief as the Court deems just and equitable.

Date: October 13, 2006

By:

/s/Daniel M. Mulholland III

Daniel M. Mulholland III

Henry M. Casale

Horty, Springer & Mattern, P.C.

4614 Fifth Avenue

Pittsburgh, PA 15213

412-687-7677

Attorneys for Defendant

Bradford Regional Medical Center